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17. The method of claim 15, wherein the disease is allergic conjunctivitis.
18. The method of claim 15, wherein the disease is vernal conjunctivitis.
19. The method of claims 14, 15, 16, 17 or 18, wherein said active ingredient is nedocromil sodium.

REMARKS

Claims 1 – 13 were pending. Claims 1 – 13 have been rejected. The Examiner has noted the absence of a statement according to 37 C.F.R. 3.73(b). An appropriate statement has now been provided. The Examiner has also noted that Applicants have failed to comply with 37 C.F.R. 1.121(b) in amending claim 4. As the Examiner suggested, Claims 4 – 9 have been cancelled and new claims 14 – 19 have been added in compliance with 37 C.F.R. 1.121(b). Claims 14 – 19 are identical in all respects to Claims 4 – 9 except that Claim 14 includes the amendments to Claim 4 that Applicants attempted to make in their Response to the Office Action Dated April 10, 2000.

The Recapture Rejection:

The Examiner has rejected claims 1 – 13 under 35 U.S.C. § 251 on the ground that Applicants are impermissibly attempting to obtain claims in a reissue application that are broader than the subject matter which was surrendered during prosecution of the original patent. Applicants respectfully traverse this rejection and request that claims 1 – 3, and 10 – 19 be examined on the merits.

Broadly, the recapture rule bars a patentee from acquiring, through reissue, claims that are of the *same* or *broader* scope than those claims that were cancelled from the original application. *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 995 (Fed. Cir. 1993); *Ball Corp. v. United States*, 729 F.2d 1429, 1436 (Fed. Cir. 1984). However, reissue claims that are broader than the original claims

in certain respects but narrower in others may nevertheless avoid the effect of the recapture rule. *Patecell v. United States*, 12 U.S.P.Q.2d 1440 (Cl. Cl. 1989); *Mentor*, 998 F.2d at 996.

The recapture rule does not bar the patentee from securing reissue of claims that are broader than a cancelled claim if the reissue claim is also narrower than the cancelled claim in a way that is material to the alleged "error."¹ *Patecell*, 12 U.S.P.Q.2d at 1447. Similarly one cannot presume merely from the act of canceling a claim that a patent applicant made a deliberate judgment that a second claim that is narrower in a certain respect than the cancelled claim would also be unpatentable. *Id.* In fact, even if the applicant deliberately cancelled a particular claim because it was unpatentable does not necessarily mean that a claim that is broader in some ways and narrower in others would be unpatentable. *Id.* Therefore, as long as the reissue claims are narrower than the cancelled claim in a way that is material to the "error," the reissue claims escape the recapture rule.

Stated another way, "[u]nder the recapture rule, claims that are broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution are impermissible." *Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472, 1480 (Fed. Cir. 1998). There are two steps in the analysis under this broad rule. First, it must be determined "whether and in what respect the reissue claims are broader than the original patent claims." *Id.* Second, if the reissue claims are in fact broader than the original patent claims, it must be determined whether the broader aspects relate to surrendered subject matter. *Id.* However, if the reissue claim is narrower, in all aspects, than the cancelled claim, the recapture rule simply does not apply. *In re Clement*, 131 F.3d 1464, 1470 (Fed. Cir. 1997).

¹ It is important to understand the nature of the "error" in this case. As stated in the declarations of the inventors filed in this case, the originally filed claims in this case were directed to treatment of many diseases. (Clark Decl. ¶ 7; Wright Decl. ¶ 7; Ratcliffe Decl. ¶ 7.) Those claims were cancelled and, in their stead, a claim directed to one specific disease (reversible obstructive airways disease) was added. (Blakely Decl. ¶4.) Through

As to Claims 1 – 3, the subject matter of these claims was never surrendered during prosecution. These claims are identical to those that issued in the '833 patent. Clearly, the subject matter of an issued claim can not have been surrendered. The recapture rule is therefore inapplicable.

The Examiner states that Claims 4 – 13 (now 10 – 19) were present in the prosecution of the original application, but were cancelled, and therefore, these claims are drawn to subject matter that was surrendered during prosecution of the original patent application. Applicants respectfully disagree with the Examiner. Claims 10 – 19, which replace now cancelled Claims 4 – 13, are in all aspects narrower than the claims that were cancelled during prosecution of the original application.

During the prosecution that led to issuance of the '833 patent, in application serial number 08/082,804, Applicants cancelled Claim 18. Cancelled Claim 18 recited a method for the treatment of thirteen different diseases. Cancelled Claim 18 also broadly recited administering a certain pharmaceutical solution "to a patient," and did not specify a specific organ of the patient to be treated. Furthermore, cancelled Claim 18 did not specify any particular amount of solution that was to be administered to the patient. Finally, cancelled Claim 18 did not specify that the solution was to be ophthalmically acceptable.

In stark contrast, both independent Claims 10 and 14 (replacing cancelled Claim 4) of the present application are directed to a method for treatment of a disease chosen from a much smaller list of diseases. In the case of claim 10, only one disease is listed, as to claim 14, only four diseases are listed. Bearing in mind the format in which these claims are written, the omission of some of the diseases from the original group of diseases acts to narrow the scope of the claim. Further, Claims

inadvertence and mistake, the attorneys prosecuting the patent application failed to file a continuation application claiming treatment of the diseases now recited in the reissue claims. *Id.* ¶¶ 5 – 10.

10 and 14 recite that administration of the pharmaceutical solution is to the "eye," as opposed to the "patient" in general. Cancelled Claim 18 allowed for the possibility of administration to virtually any part of the patient. The present recitation of "eye" in Claims 10 and 14 significantly narrows the scope of the claims as compared to the claims that were cancelled. Claims 10 and 14 also recite an amount of solution that is to be administered—an effective amount. Whereas cancelled Claim 18 merely recited a "unit dose" of the solution, present Claims 10 and 14 require that an effective amount be administered—this is clearly a narrowing limitation. Finally, the solution recited in claims 10 and 14 must be "ophthalmically acceptable." This limitation clearly narrows the scope of aqueous pharmaceutical solutions which might read upon claims 10 or 14.

In sum claims 10 and 14 are narrower than cancelled Claim 18 in all aspects. The group of diseases to be treated is narrower; the specific organ of the patient to be treated is narrower; a new limitation as to the amount of the solution has been added; and the solution to be administered has been narrowed. Each and every element of cancelled Claim 18 has been narrowed. Therefore, under applicable law, e.g., *In re Clement*, since reissue claims 10 – 19 are narrower in all aspects than the claim cancelled in the prior application, the recapture rule does not apply.

Moreover, even if the Examiner finds that the reissue claims are not narrower than cancelled Claim 18 in all aspects, the fact remains that the reissue claims are narrower than cancelled Claim 18 in a manner that is directly relevant to the "error" alleged in this case. As explained above in footnote no. 1, the "error" here was Applicant's attorneys' inadvertent failure to continue the prosecution of claims directed to treatment of ophthalmic conditions. As originally filed, cancelled Claim 18 recited treatment of thirteen separate medical conditions, a small subset of which were ophthalmic conditions. As issued, Claim 1 of the '833 patent only recites the treatment of one of those diseases. Applicants' attorneys erred by failing to prosecute claims reciting treatment of the


other diseases. Claim 10 only recites the treatment of one disease, and claim 14 recites the treatment of only four diseases. These claims are therefore narrower than cancelled claim 18, and this narrowed scope is directly relevant to the claimed "error." Therefore, under applicable law, e.g. *Patecell*, the recapture rule does not bar the present reissue claims.

For the reasons stated, Applicants respectfully request that claims 1 - 3, and 10 - 19 be examined on their merits and allowed in due course.

Statement Under 37 C.F.R. 3.73:

Pursuant to 37 C.F.R. 3.73(b), by and through its undersigned attorneys, such attorneys having the power to act on its behalf in this matter, Fisons plc hereby states that it is the assignee of all right, title and interest in United States Patent Number 5,443,833, and that it has the right to take action in this matter before the United States Patent and Trademark Office. Evidence of such ownership may be found in the records of the United States Patent and Trademark Office at Reel 4864, frame 113.

Respectfully submitted,



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